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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,423	06/11/2001	Arnthor Acvarsson	2739.2004-001	4246

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,423

Applicant(s)

AEVARSSON ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 5, 18-20 and 25-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2 IDSs.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-37 are pending.

Response to restriction requirement filed 10/20/2004 is acknowledged. Applicant elected, without traverse, Group I, claims 1-24. Claims 25-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 25-37 is requested.

In regard to election of species requirement, applicant elected claim 3, item (b) - minimum percentage of predetermined amino amino acid residues as selection criteria. Claims reading on the elected species are 1-4, 6-17, 21-24, claims 1,2, 6-17, 21-24 being generic. Claims 5, 18-20 are withdrawn from consideration as drawn to non-elected species.

Information Disclosure Statement

2. Applicants' Information Disclosure Statements filed 06/11/2001 and 09/04/2001 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of
35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 6-17,21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

A. Claim 1: The objective of the method stated in the claims is not clear: It seems that the "candidate protein" has characteristics of facilitating crystallization not of some other protein but itself. It is not clear how protein facilitates crystallization of itself.

B. Claim 2: The claim is confusing in that the objective of the method, facilitating process of structure determination, is different from the objective of the base claim. Note that facilitating process of structure determination, e.g., by electron-spin resonance, does not necessarily coincides with facilitating of protein crystallization.

C. Claim 6: The claim is very confusing: What is the meaning of "suspected of coding"? – anything can be "suspected" of coding at least a part of any protein.

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D. Claim 21: The term "active site of a protein family" is not clear. Usually, active site is a part of a protein, rather than of a protein family.

E. Claims 22,23: The claims lack antecedent basis reciting "protein family": there is no "protein family" addressed in the base claims 1,6.

F. Claim 22: the phrase "protein family comprises a protein in a pathogenic organism" is not clear. Should it be "protein family comprises a protein from a pathogenic organism"

G. Claim 24: It is not clear how "a protein with unknown structure" can be "linked to a disease".

Claim Rejections - 35 U.S.C. § 101/ 112-1

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

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C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

4. Claims 1-4, 6-17,21-24 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claims are drawn to method for obtaining candidate proteins. Specification informs that the invention provides methods to access very broad natural diversity and select directly from nature proteins with physical properties suitable for crystal structure determination. The method is not dependent on the current availability of genes but can generate a large input of genes from different species including genes from uncultivable and unknown species. See p. 4, bottom. Thus, apart from potentially being able to crystallize, there is no specific utility identified for any particular protein. Identifying any potential utility will require further research; thus, the invention lacks substantial utility. The specification does not relate to any "real world" substantial utility of the claimed method.

5. Claims 1-4, 6-17, 21-24 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a

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credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4, 6-17, 21-24 are rejected under 35 U.S.C. 112, first paragraph, as not being enabling. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims, to the extent they read on the elected species, are drawn to method for obtaining candidate proteins that would have desired characteristics to facilitate their own crystallization, the method comprising: isolating nucleic acids from a microorganism sample, sequencing nucleic acid samples, selecting from the obtained nucleic acid sequences one or more target sequences based on minimum percentage of predetermined amino acid residues, and then expressing protein of interest that have characteristics that facilitate crystallization. In regard to selection criteria based on minimum percentage of predetermined amino acid residues in a putative protein, specification teaches (paragraph bridging pages 6-7) that:

A useful selection criterion for the target sequences is a predetermined minimum of one or more amino acid residues. In particular, a minimum ratio of polar amino acid residues may be beneficial for solubility, crystallization and structure determination, such as more than about 4% of a given amino acid, including more than about 3.5%, such as more than about 3%. Such amino acids residues include Asp, Gln, Glu, Asn, His, Lys and combinations thereof

There is no guidance on how presence of certain residues, and in certain amounts per protein molecule, reflects on ability of the putative protein to crystallize . It remains unclear from the cited description whether the presence of particular residues is beneficial for solubility or for crystallization. There are no working examples demonstrating selecting nucleic acids to be expressed based on minimum percentage of predetermined amino acid residues. Nor there is guidance in prior art on how selection of a protein based on presence of a certain amount of a certain amino acid residue, e.g., of > 3.5% of Phe, determines ability of protein to crystallize . In general, prior art addresses protein crystallization from the point of view of how to select conditions to crystallize protein of interest, rather than how to select structural content of protein of unknown structure (and utility) so that such protein is more capable to crystallize.

In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

Specification

7. The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, pages 14,32,35. Applicant is requested to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(b).

Conclusion.

8. No claims are allowed

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb